



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1120]

Vaginal Microbicides: Development for the Prevention of Human Immunodeficiency Virus Infection; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Vaginal Microbicides: Development for the Prevention of HIV Infection.” The purpose of this guidance is to assist sponsors in all phases of development of vaginal microbicides, defined as vaginal drug products that prevent human immunodeficiency virus (HIV) acquisition. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of vaginal microbicides. This guidance finalizes the draft guidance issued on November 23, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charu Mullick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6365, Silver Spring, MD 20993-0002, 301-796-1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Vaginal Microbicides: Development for the Prevention of HIV Infection.” This guidance addresses nonclinical development, early phases of clinical development, phase 3 trial considerations, and safety considerations in vaginal microbicide development including safety considerations in adolescent and pregnant populations. The guidance also outlines development of combination microbicide products such as drug-drug combinations, drug-device combinations, or combination products that include microbicide and are intended for multiple indications. This guidance finalizes the draft guidance issued on November 23, 2012 (77 FR 70167). The majority of public comments submitted to the docket were related to clinical trial considerations and nonclinical pharmacology/toxicology issues. This guidance incorporates FDA responses to the public comments.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on developing vaginal microbicides for preventing HIV transmission. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under 0910-0014, and the collections of information referred to in the guidance for clinical trial sponsors entitled “Establishment and Operation of Clinical Trial Data Monitoring Committees” have been approved under 0910-0581.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 13, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-27287 Filed 11/18/2014 at 8:45 am; Publication Date: 11/19/2014]